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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/706,161   | 11/12/2003  | Gary T. Neel         | 02-1134-E            | 7574             |
| 22852  | 7590        | 01/11/2005           | EXAMINER             |                  |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER<br>LLP<br>1300 I STREET, NW<br>WASHINGTON, DC 20005 |             |                      | WALLENHORST, MAUREEN |                  |
|  |             |                      | ART UNIT             | PAPER NUMBER     |
|  |             |                      | 1743                 |                  |

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/706,161

Applicant(s)

NEEL ET AL.

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/9/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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1. The disclosure is objected to because of the following informalities: On page 2 of the specification in the section entitled "Cross-Reference to Related Applications", the phrase – now U.S. Patent no. 6,743,635, issued on June 1, 2004—should be inserted after the phrase "U.S. Patent Application no. 10/286,648, filed November 1, 2002," in order to update the status of this application.

Appropriate correction is required.

2. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 41, the "quality control strip" lacks antecedent basis since independent claim 39 recites a "check strip", not a "quality control strip". Claim 41 should use the same terminology as claim 39.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by Nankai et al (US patent no. 5,266,179, submitted in the Information Disclosure Statement (IDS) filed on August 9, 2004).

Nankai et al teach of a sensor test strip and meter for determining a glucose level in a biological fluid such as blood. The sensor is inserted into the meter in order to undergo a test. The sensor test strip 30 comprises a substrate plate 31 having thereon a counter electrode 34 and a measuring electrode 35, leads 33, 32 connected thereto and an insulating layer 36. A reaction layer containing an enzyme and a mediator for detecting glucose covers the counter electrode and measuring electrode. See Figure 7 in Nankai et al. The counter and measuring electrodes 34, 35 act as an auto-on conductor since when the sensor test strip 30 is inserted into a meter 51, a detector circuit 52 detects the insertion of the sensor by detecting current flow through the electrodes. This causes the current-to-voltage converter 53, the A/D converter 54, the temperature sensor 55 and other components of the meter to be turned on. See Figure 9 and lines 7-12 in column 9 of Nankai et al. Nankai et al teach that the meter can be adjusted by inserting an adjustment test strip in the form of a calibration test strip into the meter. The calibration test strip has a test strip-like shape with a constant resistance value. The meter is able to distinguish between a test strip and an adjustment calibration strip by reading the resistance value of the chip when inserted into the meter. When a calibration test strip is inserted into the meter, the meter measures a constant resistance value within a range assigned to the calibration strip. From this measurement, the meter distinguishes it as a calibration strip and undergoes calibration. When a test strip is inserted into the meter, the meter measures a resistance value within a range assigned

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to the test strip. From this measurement, the meter distinguishes it as a test strip. To undergo a test, a sample liquid is applied to the test strip in the meter. A constant voltage is applied to the test strip, and the resulting variation in resistance or current is measured and converted into a glucose level using a previously set calibration curve. See columns 3-4 in Nankai et al.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al (US Patent no. 5,438,271, submitted in the IDS filed on August 9, 2004) in view of Castellano et al (US Patent no. 5,925,021, also submitted in the IDS filed on August 9, 2004).

White et al teach of a biosensing meter that distinguishes between sample and check strips. A sample strip 10 comprises a pair of electrodes 12 and 14 on a polymeric support 16. A layer of enzymatic reactants overlays the electrodes 12 and 14 and provides a substrate on which an analyte-containing sample can be placed. A check strip 30 is used to determine the operability of the meter and its measurement functions. The check strip 30 also includes a pair

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of electrodes 32 and 34, which correspond in placement to the sense and excitation electrodes 12 and 14 of the sample test strip 10. The meter 50 includes a slot for accepting either the sample strip 10 or check strip 30. The meter 50 contains electrical contacts A, B, C, D for electrically contacting and conducting a current through the electrodes on the strips. When either a test strip or check strip is inserted into the meter 50, an excitation voltage is applied from a source 51 to the electrodes. The meter is able to distinguish between a test strip and a check strip by measuring the current or voltage drop between the electrodes on the strip. If the current is below a predetermined value  $i_1$ , a determination is made that the strip inserted into the meter is a sample test strip 10. If the current is above the predetermined value  $i_1$ , a determination is made that the strip inserted into the meter is a check strip 30. See columns 3 and 4 in White et al. White et al fail to teach that the electrodes on the test strip and check strip serve as an auto-on conductor to automatically turn the meter 50 on when either type of strip is inserted therein.

Castellano et al teach of a medication delivery device that includes a blood characteristic monitor therein, which determines things like the level of glucose in a blood sample. The monitor includes a test strip 204 for holding a blood sample, which is inserted into a test strip interface 206 in the monitor 202. When the test strip 204 is inserted into the interface 206, the monitor 202 and the microprocessor 32 therein are automatically activated. The monitor is caused to analyze the blood characteristic (i.e. glucose), and sends the result to the microprocessor 32 for display 34. Preferably, the blood characteristic monitor 202 uses electrochemical sensor technology (i.e. the blood sample reacts with a chemical upon the application of an electrical current). To operate the monitor 202, one fully inserts a test strip 204 into the test strip interface 206. This automatically turns on the microprocessor 32 and the

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monitor 202. Removal of the test strip 204 automatically turns off the monitor 202 and microprocessor 32. See lines 41-67 in column 14 and lines 1-32 in column 15 of Castellano et al.

Based upon the combination of White et al and Castellano et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the electrodes on the test strip and check strip taught by White et al as an auto-on conductor to automatically turn the meter 50 on when either type of strip is inserted therein, similar to the electrochemical auto-on means taught by Castellano et al, since Castellano et al teach that such a feature in an electrochemical test strip sensor device allows one to save energy in the meter conducting the test by only activating the meter into an active mode when a test strip is inserted therein for analysis. At all other times, the meter is in an inactive mode, thus conserving energy.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Lewis et al who teach of diagnostic test strips for use in electrochemical tests; and Neel et al, which corresponds to the parent application of this application.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

January 10, 2005

*Maureen M. Wallenhorst*  
MAUREEN M. WALLENHORST  
PRIMARY EXAMINER  
GROUP 1700